REMARKS

This is a request for filing an RCE and is responsive to the Final Rejection mailed on March 17, 2008. Claims 2, 9, 13, 14 19, 20, 22, and 26- 31 have been canceled without prejudice. The right to prosecute the subject matter of the canceled claims in a subsequent continuation, continuation-in-part, or divisional application is hereby expressly reserved. Claims 32-35 are newly added claims. Claims 1 and 18 have been amended. Claims 1, 3-8, 10-12, 15-18, 21, 23-25 and 32-35 are currently pending. Claims 1, 3-8, 10-12, 15-18, 21, and 23-25 and 27-31 stand rejected but reconsideration of them in view of the amendments and following remarks is respectfully requested.

The Examiner is thanked for the telephonic interview held on June 27, 2008 between Examiner Choi and Esther Kepplinger. During this interview, there was a discussion with the Examiner of the differences of the claims over the prior art and proposed amendments. The discussion was helpful and fruitful and the opportunity for such interview is greatly appreciated.

I. Claim Rejections under 35 USC § 112, First Paragraph, Written Description

Claims 27-31 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In order to expedite prosecution, the rejected claims have been canceled without prejudice. Thus, it is respectfully urged that this rejection is moot and thus should be withdrawn.

II. Claim Rejections under 35 USC § 112, First Paragraph, Enablement

Claims 18, 21, 23-25, 28, 30, 31 were rejected under 35 U.S.C. 112, first paragraph, because the Office states that the specification, while being enabling for the disclosed process of pretreating the ascorbic acid and ascorbic acid which has been pretreated according to said process in the disclosed amounts and temperatures, does not reasonably provide enablement for other processes of pretreating the ascorbic acid or ascorbic acid pretreated by other processes.

In order to expedite the prosecution of the application, the claims have been amended to recite the specifics of the pretreatment process. In view of these amendments, it is respectfully requested that the rejection be withdrawn.

III. Claim Rejections under 35 USC § 112, Second Paragraph

Claims 18, 21, 23-25, 28, 30, 31 were rejected under 35 U.S.C. 1 12, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. The alleged omitted elements were the process steps by which the ascorbic acid is pretreated.

In order to expedite the prosecution of the application, the claims have been amended to recite the specifics of the pretreatment process. In view of these amendments, it is respectfully requested that the rejection be withdrawn.

IV. Claim Rejections - 35 USC § 103(a)

Claims 1,3-8,10-12, 15-18, 21,23-25,27-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US Pat. 5,902,591), Kalus et al. and Bassford et al. (US Pat. 2,517,276).

The Office states that Schinitsky et al. teach a composition and method to reduce epidermal wrinkling comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%), and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle.

Murad is stated to teach a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such as N-acetylglucosamine or glucosamine; methionine or N-acetyl cysteine; ascorbic acid; and a zinc compound, such as zinc sulfate. The composition may be an ointment or cream; the sugar and amino acids assist in thickening the dermis and supplementing collagen which reduces wrinkling; ascorbic acid inhibits collagenase and elastase and zinc binds collagen fibers and inhibits elastase.

Herstein is alleged to teach that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule.

Kalus et al. is purported to show that ascorbic acid will form semidehydoascorbic acid in the presence of oxygen or metals.

Bassford et al. is alleged to teach methods of purifying ascorbic acid in which one of the steps includes dissolving ascorbic acid in distilled water at 60° C. It is asserted that the reference teaches that when preparing a pharmaceutical compound, it is generally advisable to effect the final

purification by crystallizing a first crop of pure material in the conventional manner which is disclosed in Experiment B.

The Office Action states that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% ascorbic acid, non-toxic zinc salt, water and a pH of 3.4 to 4.1. The Office Action states that it would have been obvious to use the pH to facilitate entry of the ascorbic acid into the skin and utilize the preparation method of Bassford et al. with the expectation of a product with sufficient purity for pharmaceutical purposes.

The Action says that Applicant cannot argue the individual references separately and that the Examiner has set forth reasons for the combination of references.

It is submitted that the amended claims are not obvious over the combination of five references cited by the examiner. ***The combination of references does not result in the invention as claimed***. Bassford et al. is cited by the examiner for the alleged obviousness of the claimed pretreatment steps. However, Bassford et al. in Examples I and V show the purification of ascorbic acid by admixing ascorbic acid, water and an organic solvent, such as toluene, distilling off all of the water and recovering the ascorbic acid as crystals from the organic solvent. The instant claims recite dissolving ascorbic acid in water at a temperature of between about 60°C to about 90°C to provide an aqueous ascorbic acid solution and cooling the aqueous ascorbic solution to below about 40°C to provide a concentrated ascorbic acid solution, which is utilized in the preparation of the claimed composition. Bassford et al. do not teach such a method and do not make it obvious. Bassford et al. always utilize an organic solvent and distill off the water and then crystallize from the organic solvent.

The examiner seems to be suggesting for the preparation of pharmaceuticals that Bassford et al. also teach Experiment B, in which Bassford et al. recovers crystalline ascorbic acid from an aqueous solution. However, it is clear from the Example V of Bassford et al. that it does not teach the pretreatment step as claimed and also that Experiment B is not an effective process. Bassford et al. teach away from this process since they indicate that the Bassford et al. process loses 14 to 15 %

of the ascorbic acid and results in decomposition and discoloration of the ascorbic acid (column 3, lines 45-48). Moreover, Experiment B does not suggest recovering a concentrated solution of ascorbic acid and using that in making preparations. Rather, Bassford et al. always teach recovering the ascorbic acid in a crystalline form.

The presently claimed compositions are neither taught nor suggested by the combined prior art references applied by the examiner.

Thus, for the reasons described above, the combined prior art does not teach or make obvious the claimed invention. It is therefore respectfully requested that the rejection of claims 1, 3-8, 10-12, 15-18, 21, 23-25, and 27-31 under 35 U.S.C. § 103(a) be withdrawn.

V. Claim Rejections - 35 USC § 103(a)

Claims 1, 3-8, 10-12, 15-18, 21, 23-25, 27-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043), Kalus et al. and Bassford et al. (US Pat. 2,517,276).

The examiner's assertions about the teachings of Schinitsky et al., Murad, Kalus et al., and Bassford et al., are set forth above and not repeated to avoid repetition.

The examiner states that Darr et teach that a pH of no more than 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form, facilitates entry into the skin and stabilizes the molecule. The examiner asserts that a 5% solution of ascorbic acid remains quite stable even at a pH of 4.5.

The Office Action states that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% ascorbic acid, amino sugar, water and a pH of 3.4 to 4.1. However, it is asserted that the combination of references would have motivated one of ordinary skill in the art to modify the prior art with the expectation that a solution of ascorbic acid at pH of about 3.5 would be stable; that the combination would be effective for treating against sun damage; and that according to the process of Bassford et al., the preparation would be sufficiently pure for pharmaceutical preparations.

It is submitted that the amended claims are not obvious over the combination of five references cited by the examiner. ***The combination of references does not result in the invention as claimed.*** Bassford et al. is cited by the examiner for the alleged obviousness of the claimed pretreatment steps. However, Bassford et al. in Examples I and V show the purification of ascorbic acid by admixing ascorbic acid, water and an organic solvent, such as toluene, distilling off all of the water and recovering the ascorbic acid as crystals from the organic solvent. The instant claims recite dissolving ascorbic acid in water at a temperature of between about 60°C to about 90°C to provide an aqueous ascorbic acid solution and cooling the aqueous ascorbic solution to below about 40°C to provide a concentrated ascorbic acid solution, which is utilized in the preparation of the claimed composition. Bassford et al. do not teach such a method and do not make it obvious. Bassford et al. always utilize an organic solvent and distill off the water and then crystallize from the organic solvent.

The examiner seems to be suggesting for the preparation of pharmaceuticals that Bassford et al. also teach Experiment B, in which Bassford et al. recovers crystalline ascorbic acid from an aqueous solution. However, it is clear from the Example V of Bassford et al. that it does not teach the pretreatment step as claimed and also that Experiment B is not an effective process. Bassford et al. teach away from this process since they indicate that the Bassford et al. process loses 14 to 15 % of the ascorbic acid and results in decomposition and discoloration of the ascorbic acid (column 3, lines 45-48). Moreover, Experiment B does not suggest recovering a concentrated solution of ascorbic acid and using that in making preparations. Rather, Bassford et al. always teach recovering the ascorbic acid in a crystalline form.

The presently claimed compositions are neither taught nor suggested by the combined prior art references applied by the examiner.

Thus, for the reasons described above, the combined prior art does not teach or make obvious the claimed invention. It is therefore respectfully requested that the rejection of claims 1, 3-8, 10-12, 15-18, 21, 23-25 and 27-31 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. If any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for additional action and response thereto. The undersigned would appreciate such interaction for efficiency.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 36091-701.302).

Respectfully submitted,

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